

**SUBJECT: PROTECTION OF HUMAN SUBJECTS**

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**PURPOSE AND SCOPE**

Research using human subjects provides important medical and scientific benefits to individuals and to society. The need for this research does not, however, outweigh the need to protect individual rights and interests. Department of Energy (DOE) policy regarding this issue is established in the Federal Policy for the Protection of Human Subjects, adopted by DOE June 18, 1991, as Title 10 Code of Federal Regulations (CFR) 745, Protection of Human Subjects. The purpose of this Policy is to establish DOE-specific principles for the protection of human subjects involved in DOE research.

This Policy cancels and supersedes DOE P 443.1, *Protection of Human Subjects*, dated 5-15-00.

**POLICY**

DOE research is conducted by or for DOE institutions, supported with DOE funds, or performed by DOE employees (including the National Nuclear Security Administration) whether done domestically or in an international environment and includes classified and proprietary research. Regulations and directives that specifically address the protection of human subjects include 10 CFR Part 745; 45 CFR Part 46, Subparts B, C, and D; Department of Health and Human Services Regulation on Protection of Human Subjects; and DOE O 443.1A, *Protection of Human Subjects*, dated 12-20-07. The requirements of all applicable regulations and directives must be met before any research involving human subjects is initiated.

In addition to traditional biomedical and clinical studies, such research includes but is not limited to studies that—

- use humans to examine devices, products, or materials with the express purpose of investigating human-machine interfaces or evaluating environmental alterations when humans are the subjects being tested;
- use personally identifiable bodily materials such as cells, blood, tissues, urine, or hair, even if the materials were collected previously for a purpose other than the current research;
- collect and use personally identifiable information such as genetic information or medical and exposure records, even if the information was collected previously for a purpose other than the current research;
- collect personally identifiable data, surveys, or questionnaires through direct intervention or interaction with individuals; and

- search for generalizable<sup>1</sup> knowledge about categories or classes of subjects (e.g., linking job conditions of worker populations to hazardous or adverse health outcomes).

Human subject research does not include the following:

- studies to improve the safety or execution of procedures that apply to routine occupational activities;
- occupational health surveillance of DOE Federal and contractor employees to determine apparent departures from typical health status and not for the purpose of obtaining generalizable knowledge; and
- employee surveys used as management tools to improve worker or contractor performance as long as the identity of the participant is protected.

## RESPONSIBILITY

All DOE employees, contractors, and financial assistance recipients share the responsibility to protect the rights and welfare of human research subjects. The Secretary of Energy is responsible for the conduct of DOE-related human subjects research. The requirements for implementing this policy are described in DOE O 443.1A to ensure that the research program keeps pace with the changing and complex nature of human subjects research, develops and implements comprehensive educational programs, and performs program compliance reviews. Any new proposal for research with human subjects requires that the Institution administering the Institutional Review Board (IRB) for review and approval of the proposal hold a valid Federalwide Assurance (FWA) from the Department of Health and Human Services Office of Human Research Protections.

BY ORDER OF THE SECRETARY OF ENERGY:



CLAY SELL  
Deputy Secretary

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<sup>1</sup> New information that has relevance beyond the population or program from which it was collected, or information that is added to the scientific literature.